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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) <i>Bio Core 260</i>	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]		Application Number <i>10/809,140</i>	Filed <i>3/25/2004</i>
on <i>12-9-05</i>	Signature <i>Collen Board</i> <i>575-273-8700</i>	First Named Inventor <i>Chaouk</i>	
Typed or printed name <i>Collen Board</i>	Art Unit <i>1732</i>	Examiner <i>Daniel's</i>	
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the		<i>Collen Board</i> Signature	
<input type="checkbox"/> applicant/inventor.		<i>Collen Board</i> Typed or printed name	
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/98)		<i>404 373 5065</i> Telephone number	
<input checked="" type="checkbox"/> attorney or agent of record. Registration number <i>38,824</i>		<i>12-9-05</i> Date	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____			
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input checked="" type="checkbox"/> *Total of <i>1</i> forms are submitted.			

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of Chaouk et al.

Filing Date: March 25, 2004

Examiner: Daniels, M.

Serial No.: 10/809,140

Art Unit: 1732

Title: Hydrogel String Medical Device

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450  
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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

The following comments are submitted in response to the Office Action mailed on September 9, 2005 and the advisory action mailed on November 29, 2005. This Request for Review is accompanied by a Notice of Appeal and a Credit Card Payment Form for the required payment.

**The Pending Claims**

Claims 1-8 are pending in the application. The claims as pending are listed in the Response to Office Action filed on November 16, 2005.

**The Rejection**

Claims 1-8 stand rejected under §103(a) as obvious over U.S. 6,152,943 to Sawhney ("Sawhney") in view of U.S. Patent No. 5,443,454 to Tanabe ("Tanabe"). The rejection is traversed.

**The Claimed Invention**

The claimed invention is a method for forming a hydrogel string. The method uses a delivery device having a gelation chamber in which a prepolymer and a gelation initiator are combined to form the hydrogel. The hydrogel is then extruded from the delivery device as a string. In other words, the hydrogel is not formed in the body per se but rather in the delivery device.

Claims 2-5 and 8 specify that the delivery device is a catheter (claim 2); a multilumen catheter (claim 3); a multilumen catheter having a gelation chamber (claim 4); or a coaxial dual

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lumen catheter where the inner catheter is slidable within the outer catheter and controls the gelation of the hydrogel string (claim 8).

Claim 6 specifies that the prepolymer composition is at least two solutions that form a hydrogel when combined.

Claim 7 specifies that the hydrogel is extruded from one end of the gelation chamber as the prepolymer is moved into the other end of the gelation chamber.

**The rejection of claims 1-8**

Only one rejection remains, the rejection of all claims as obvious over Sawhney in view of Tanabe.

Sawhney teaches a method and device for forming a hydrogel in situ- in a body cavity or void. Sawhney teaches away from premature formation of the hydrogel, meaning formation of the hydrogel before it is at the body cavity or void. This point of the invention is stated very clearly several times, such as in the abstract "deliver two or more fluent prepolymer solutions without premature crosslinking" and col. 1, lines 8-10 "delivering two or more liquid components to form a hydrogel implant in situ".

The paragraph beginning at col. 3, line 7 reads:

In accordance with the present invention, delivery systems are provided for delivering separate prepolymer components of a hydrogel system, without premature crosslinking within the delivery system. In one embodiment, the delivery system includes an occlusive element for anchoring a distal end and isolating the region in which the hydrogel is to be formed in situ. In another embodiment, the delivery system may include variable stiffness regions to enable passage through tortuous anatomy. In yet another embodiment, the delivery system includes a steerable tip. In still further alternative embodiments, the prepolymer components of the hydrogel system may be mixed together in a mixing chamber disposed in a distal region of the delivery system, and then extruded into the body lumen or void during the crosslinking process, to reduce washout or dilution of the components. (emphasis added)

The embodiment illustrated by Figure 3, which has been discussed in the prior Response as well as in the latest Office Action is one embodiment of the delivery systems- all of which are used to deliver a hydrogel system without premature crosslinking.

The embodiment of Figure 3 is discussed further at col. 10, lines 1-25:

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Delivery system 40 therefore prevents premature crosslinking of the prepolymer solutions, while also enabling the solutions to be mixed and partially gelled before being deposited in the body lumen or void. Delivery system may be especially useful in depositing hydrogel systems that form both physical and chemical crosslinks, wherein the physical crosslinking is accomplished by mixing the prepolymer solutions in mixing chamber 46. The partial gel extruded from mixing chamber 46 through outlet ports 47 then may have sufficient mechanical integrity to remain in position in the body lumen or void during the chemical crosslinking process. (emphasis added)

The Office Action argues that the "partially formed" gel extruded from the mixing chamber would "obviously or inherently existed with some string-like characteristics." This is an unsupported statement. There is no statement in Sawhney to support this statement. In fact the opposite is true- all statements in Sawhney teach away from this statement. Perhaps the primary definition for "extrude" found in the online edition of Merriam-Webster's dictionary <http://www.m-w.com/dictionary/extrude> should be used: "1 : to force, press, or push out". A glob of partially formed gel can be "extruded" from a catheter, and this is more likely what is taught by Sawhney. A glob of partially formed gel pushed from a catheter could have a number of "shapes" or no shape at all. The Examiner's statement that it would "obviously" have "string-like characteristics" is baseless.

The Office Action argues that there is motivation to combine the teachings of Sawhney and Tanabe. The Applicants have pointed out how Sawhney teaches away from the claimed invention. Sawhney teaches away from forming the hydrogel within the catheter and extruding it from the catheter as a string. Sawhney explicitly teaches avoiding premature crosslinking of the hydrogel.

The Examiner argues that this aspect of the claimed invention is taught by Tanabe and that one of ordinary skill in the art would have combined the method of Tanabe with that of Sawhney in order to eliminate the dispersing and leakage of an embolic agent out of the site.

Sawhney already has recognized and provided a solution to the problem of dispersion-delivering a partially polymerized product. One of skill in the art in reading Sawhney would not be motivated to provide a solid composition as taught by Tanabe since Sawhney already teaches a solution. Furthermore, Sawhney specifically teaches to not deliver a solid hydrogel.

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The Examiner is improperly engaged in hindsight to modify Sawhney to reproduce the invention that is claimed. In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985); W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein only that which the inventor taught is used against its teacher").

Since the cited references do not anticipate or render obvious the claims, the issuance of a notice of allowance is respectfully requested.

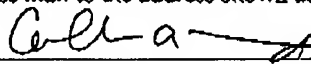
Respectfully submitted,

  
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**Certificate of Transmission Under 37 C.F.R. §1.8(a)**

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Collen A. Beard

Date: December 9, 2005

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